

A research undertaking of the magnitude of the National Children's Study raises immediate economic questions. How much does a study of this size cost? What is the true "return on investment" in terms of the nation's health and economy?

New findings in medical research make the news every day, be it gene therapy, bionic hearts, the regeneration of nerve cells, or the latest breakthrough in real-time medical imaging. As discoveries become practical tools, they help confirm that funding for medical research is a sound investment. But at this start of a new century, biomedical research is facing some of its most significant challenges. Although the goals of health research are clear—realizing health benefits for all people—the debate over cost continues in all quarters, from health care professionals and researchers to policy makers, educators, and concerned citizens.

BUILDING THE NATIONAL CHILDREN'S STUDY

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RESEARCH AS AN INVESTMENT

A useful way to consider benefits of health research is in terms of "health care costs saved." A 1995 report from the *Federation of American Societies of Experimental Biology Journal* estimated that \$68 billion in annual savings are attributable to medical research due to reduced or avoided hospital stays, or new and improved advancements in medications and medical procedures. The report concluded that for every research dollar invested, two to three dollars are returned to the economy.

Specific economic advantages of the National Children's Study—which is projected to cost an average of \$100 million per year, or \$2.7 billion over 25 years—can be viewed from the perspective of direct cost reduction. Five of the Study's major health outcome theme areas encompass diseases and conditions that currently create a societal burden of more than \$750 billion per year. This figure is all the more troubling because it represents both treatment and intervention for conditions that research has shown can be mitigated and possibly prevented.

Previous studies, similar in some ways to the National Children's Study, have demonstrated significant economic benefits. For instance, groundbreaking 1970s research on the effects of lead on children's neurodevelopment prompted the phasing out of lead

in gasoline, paint, and other products. ¹⁶ It has been estimated that the economic gain from this change is between \$110 billion and \$319 billion among each year's cohort of two-year-old children in terms of expected lifetime earnings. ¹⁷ Studies that found a link between low folate intake and neural tube defects resulted in food supply fortification and recommendations for women to take vitamin supplements as prevention strategies. ¹⁸ These measures have produced tangible economic benefits as well; for example, the annual net economic benefit of fortification has been estimated to be \$94 million. ¹⁹

In addition to health care costs saved, an important but less quantifiable economic aspect is human potential realized due to optimal health. Healthier children have greater school attendance, learn better, and are more likely to grow up to be productive workers and family members. By generating findings that can help children grow into healthy and dynamic adult members of society, the National Children's Study will yield a valuable "return on investment." What we have now, as a result of the Framingham Heart Study, is a powerful link between scientific data and health care practice. In mounting a complex, multifaceted, collaborative medical study involving thousands of participants, Framingham researchers not only broke new ground, but also learned that research provides benefits that can only be partially understood when a study begins.



A sustained research effort would greatly improve the understanding of diseases and could stimulate innovative strategies to limit the impact of conditions, ultimately reducing the nation's health care costs.

ANNUAL COST TO THE UNITED STATES FROM DISEASE BURDEN



Note: The above figures are adopted from a range of sources that may have used varying methods and assumptions in calculations.

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Several major studies have used a longitudinal (following people over time) design, including the landmark Framingham Heart Study launched after World War II. These studies—four of which are ongoing—take advantage of observations unfolding over many years to better understand the development of certain diseases and conditions.

The Collaborative Perinatal Project, launched in 1959 by the NIH's National Institute of Neurological Diseases and Blindness (now the National Institute of Neurological Disorders and Stroke), followed more than 40,000 pregnant women and their children until 1974. The study contributed some of the most important information ever collected on rubella during pregnancy,²⁰ as well as some of the first understandings of the effects of fetal exposure to alcohol and lead. It also demonstrated that febrile seizures in infancy do not demand treatment and improved our understanding of cerebral palsy. The Collaborative Perinatal Project was one of the first studies to yield insights on SIDS.²¹ Data from the study created an important resource on many children's health issues, including the impact of pregnancy outcomes and the effects of social and economic variables on the health of individual children.

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The Framingham Heart Study is the longestrunning U.S. study involving a large number of participants (57 years with more than 10,000 participants).²² Launched in 1948 under the auspices of the NIH's National Heart Institute (now the National Heart, Lung, and Blood Institute), the Framingham Heart Study is the prototype for longitudinal medical studies. It identified cigarette smoking, overweight and obesity, elevated cholesterol and blood pressure levels, and lack of exercise as risk factors for heart disease. 23-27 The challenges accepted by the study's originators have long since translated into significant health improvements for people around the world,28 and literally billions of dollars have been saved through reduced health care costs.29

The findings from the Framingham Heart Study revealed that high blood pressure is a risk factor for stroke as well as heart disease (1961, 1970); that women's risk for heart disease increases after menopause (1976); and that psychological and social factors have profound effects on heart health (1978).³⁰

The Bogalusa Heart Study, the longest and most detailed children's heart health study, was launched in 1972 and is scheduled to end in 2005. Focusing on participants from birth to age 31, it has confirmed that high blood pressure and heart disease can begin in childhood (with documented effects as early as age five), and that the nature of heart disease risk factors among children differs from that of adults. The study has also validated connections between environmental factors and

overweight, obesity, elevated cholesterol, and blood pressure levels in children.^{31, 32}

[The] Framingham [Heart Study] gave us the link between diet and heart attacks, between stroke and cholesterol. The findings translated immediately to the medical community. Doctors stopped smoking and told their patients to stop too. Big studies are costly but yield enormous benefits.

Phil Landrigan, M.D., M.Sc., professor and chairman, Department of Community and Preventive Medicine, Mount Sinai School of Medicine

The Nurses' Health Study, launched in 1976, looked at the risk factors for major chronic disease in women. The Nurses' Health Study II was launched in 1989 as a long-term evaluation of the effects of oral contraceptives, diet, and lifestyle factors on women's health. Each study has involved more than 100,000 nurses and has verified that heart disease risk is reduced among women who take a daily multivitamin; that women who eat certain types of fish on a regular basis have a lower incidence of heart disease; that healthy lifestyles significantly lower the incidence of heart disease; and that cigarette smoking is associated with increased heart-disease risk, particularly among women with diabetes.³³

The Women's Health Initiative, launched in the mid-1990s, is an observational study of 150,000 postmenopausal women between the ages of 50 and 79 over a 15-year span. The study focuses on hormone therapy (HT), diet, calcium, and Vitamin D supplementation, and the relationships of these

factors to heart disease, breast and colorectal cancer, and osteoporosis. The Women's Health Initiative has already offered insights on estrogen plus progestin HT, noting that this particular type of therapy is associated with an increased incidence of stroke and dementia.³⁴

As each of these major studies demonstrates, size and complexity are necessary to reveal the intricate patterns of human biology, as well as the subtle relationships between causes and effects that can be expressed as diseases. These multifaceted research efforts, which involve thousands of participants, continue to provide keys to medical knowledge and

clinical care, as they remind us of the powerful links between scientific data and health care practice.

The Collaborative Perinatal Project taught us that the major causes of cerebral palsy occur earlier in pregnancy than the time of birth. This study found that inflammation of the placenta is a major cause of preterm birth and found it 25 years before the idea came to be popular in the 1980s. The study was also very influential in how we manage jaundice in babies, even today.

Mark Klebanoff, M.D., director, Division of Epidemiology, Statistics, and Prevention Research, NICHD



BUILDING THE NATIONAL CHILDREN'S STUDY



Closing the gaps in health among the nation's children is among the federal government's highest health priorities. In its efforts to promote health and prevent disease, the government seeks to ensure that all Americans benefit equally from advances in quality of life. It also seeks to eliminate health disparities, specifically those based on gender, race, and ethnicity; income and education; and disability. The nation recognizes that, although great strides have been made in addressing health disparities, much work remains.

The Children's Health Act of 2000 calls upon the National Children's Study to involve diverse populations, and to assess health disparities among the nation's children. The Study will help uncover differences among groups of people in terms of health, health care access, and disease rates, allowing disparities to be identified and addressed. The Study participants will be as representative as possible of the overall U.S. population at the beginning of the 21st century—a population much more diverse than even a decade ago, and becoming more so each year.

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Sociodemographic characteristics offer a compelling portrait of the nation's children in a time of growing diversity and enhanced risk of disease among a range of ethnic groups. Over the last decade the African American population increased faster than the total population,³⁵ and Hispanics became the nation's largest ethnic minority group³⁶ (with Hispanic children accounting for one of every six children in the United States³⁷). Meanwhile, the percentage of Asian American/Pacific Islander children doubled (from 2 percent to 4 percent) in the last 20 years.³⁸

But despite vigorous population growth, many American children today face significant health challenges related to an array of factors. Some children confront poverty and poor access to health care, as well as violence, language barriers, and exposures to air and water pollution. In growing numbers, they also face diseases—such as diabetes and heart disease—exacerbated by high-fat diets and lack of physical activity.

A few select facts underscore the pressing need for greater knowledge about the health and well being of our nation's children. Mexican American boys are most affected by obesity. Puerto Rican children have the highest prevalence of asthma—11 percent—of any

U.S. ethnic group.^{39, 40} African American children are more likely to live in poverty than their white peers.^{41, 42} And African American adolescents succumb to violent death at a homicide rate six times higher than that of white adolescents.⁴³ Type 2 diabetes is a growing problem for American Indian/Alaska Native adolescents, who have the highest rates of any U.S. ethnic group.^{44,45} This population is also suffering from depression and substance abuse disproportionately, with a suicide rate 1.5 times the national rate.^{46,47} In addition, American Indian/Alaska Native infants are unduly burdened by Fetal Alcohol Syndrome, with an incidence at least twice the national average.⁴⁸

A major challenge [in the Study] will be having a balanced sample representing the U.S. as it is now. You are going to see emerging populations over the next 20 years. The Latino population and other ethnic groups are growing extremely fast, and we are going to have to account for the changing demographics of the United States.

Tom Curtin, M.D., chief medical officer, National Association of Community Health Centers

By mounting a broad-scale investigation of our increasingly diverse nation of children, the Study can learn from the socioeconomic and health successes of the last two decades. For example, over



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NATIONAL POPULATION ESTIMATES FOR CHILDREN UNDER AGE 18

Reporting One Race	Number of Children
White	55,920,453
African American	11,355,348
American Indian/Alaska Native	874,416
Asian	2,772,235
Native Hawaiian and Other Pacific Islander	148,927
Reporting Hispanic or Latino Origin*	
Hispanic or Latino	13,588,755

^{*} U.S. Census Bureau population estimates as of July 1, 2003. The U.S. Census considers race and Hispanic origin two separate concepts and therefore Hispanics may be of any race or races. Source: U.S. Census Bureau (2004). *National population estimates characteristics* [Electronic version]. Retrieved September 22, 2004, from http://www.census.gov/popest/national/asrh/NC-EST2003-asrh.html

the last 20 years there have been significant gains in the number of Hispanic middle-class households,⁴⁹ and today more than half of African American married couples have incomes higher than \$50,000.⁵⁰ Improved birth weights are evident among Hispanic infants, and their mortality rates are close to those of non-Hispanic white infants.⁵¹ Infants born to Asian American/Pacific Islander mothers have the lowest infant mortality rate of any U.S. ethnic or racial group overall.⁵² In addition, low birth weight babies are less common (6.0 percent) among American Indian/Alaska Natives than all children combined (the national rate is 7.3 percent).⁵³

By adding to and analyzing these kinds of data more comprehensively than ever before, the National Children's Study can develop the insights needed to answer pressing questions about the full range of racial, ethnic, and socioeconomic contexts that compose the national fabric. The Study will bring a unique and balanced power to the examination of diversity. To realize this opportunity fully, the Study will seek the participation of a varied group of families—particularly the women and children as pivotal contributors. To ensure that health disparities are adequately addressed, the National Children's Study will recruit extra participants from some diverse populations. Study coordinators will identify women through multiple venues, from doctors' offices and community clinics, to social service and community groups. Study information will be disseminated through many outlets, including churches, libraries, retail outlets, and community centers. And, because participant retention can be more difficult for families dealing with poverty, transportation problems, and geographic isolation, the National Children's Study will develop ways to make participation easier for them.